

- 1 -

"A DEVICE"Introduction

5 This invention relates to a surgical device. In particular it relates to a surgical device for retracting a wound opening and sealing the retracted wound opening.

Statements of Invention

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According to the invention there is provided a seal comprising a first sealing member and a second sealing member, each sealing member having an accessway to facilitate access from one side of the sealing member to the other side of the sealing member, the accessways being offset to facilitate sealed access of an object through the sealing members.

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In one case the accessway comprises an opening in the sealing member. Preferably the opening is located substantially centrally in the sealing member.

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In another case the accessway comprises a passageway extending by the sealing member. Preferably the passageway is located substantially at an edge of the sealing member.

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In one embodiment at least one sealing member is manipulable to facilitate alignment of the accessways. Preferably the sealing member is at least partially of a flexible material. The sealing member may be at least partially of a resilient material. Ideally the sealing member is of silicone or latex.

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In a preferred case the first sealing member is coupled to the second sealing member. Ideally the seal comprises a ring to which both the first sealing member and the second sealing member are coupled.

The seal may comprise means to bias the first sealing member and the second sealing member towards one another. Preferably the biasing means comprises a magnet coupled to each sealing member.

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The seal may comprise three or more sealing members.

Desirably the sealing member comprises a sheet.

10 In another aspect the invention provides a seal comprising a first sealing member and a second sealing member, each sealing member having an accessway to facilitate access from one side of the sealing member to the other side of the sealing member, and a closure member movable between a sealing position in which the closure member occludes at least one accessway and an access position in which the  
15 accessways are at least partially open for passage of an object therethrough.

In one embodiment the seal comprises means to bias the closure member towards the sealing position. Preferably the biasing means comprises one or more resilient members. Ideally the resilient member comprises an elastic band.

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The closure member may be located between the first sealing member and the second sealing member. Ideally the seal comprises at least one tether to prevent passage of the closure member through the accessway.

25 In a preferred embodiment the first sealing member is coupled to the second sealing member. Ideally the seal comprises a ring to which both the first sealing member and the second sealing member are coupled.

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The accessway in the first sealing member and the accessway in the second sealing member are preferably aligned. The accessway may comprise an opening in the

- 3 -

sealing member. Ideally the opening is located substantially centrally in the sealing member.

5 In one case the sealing member comprises a collar around the opening. Preferably the collar is provided on a side of the sealing member opposite to the closure member.

Desirably the closure member comprises a ball. The ball may be spherical.

The sealing member preferably comprises a sheet.

10 The invention also provides a further aspect a seal comprising a first sealing member and a second sealing member, the sealing members being configured to overlap one another such that a portion of the first sealing member overlaps a portion of the second sealing member along a first overlap region and a portion of the second sealing member overlaps a portion of the first sealing member along a second overlap region.

15 In one embodiment at least one sealing member is manipulable to facilitate sealed passage of an object between the sealing members. Preferably the sealing member is manipulable to facilitate sealed passage at the junction of the first overlap region and the second overlap region. Ideally the sealing member is at least partially of a flexible material. Most Preferably the sealing member is at least partially of a resilient material. The sealing member may be of silicone or latex.

20 In another embodiment the area of the first overlap region is substantially equal to the area of the second overlap region.

25 The first sealing member is preferably coupled to the second sealing member. Ideally the seal comprises a ring to which both the first sealing member and the second sealing member are coupled.

30 The sealing member may comprise a sheet.

In another aspect of the invention there is provided a seal comprising a sleeve through which an object may be passed, and means to bias the sleeve into a closed configuration. The biasing means may be provided integral with the sleeve.

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Ideally the sleeve is configured to curl-up upon itself to the closed configuration.

The sleeve may alternatively be configured to twist-up upon itself to the closed configuration.

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In one case the seal comprises a platform to which the sleeve is coupled. The platform is preferably of an annular shape. Ideally the platform comprises a stiffening ring.

The invention also provides a surgical device comprising a seal of the invention

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In another aspect the invention provides a surgical device comprising a proximal seal and a distal seal, the distal seal comprising a seal of the invention.

The proximal seal may comprise a lip seal, or an iris valve.

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According to another aspect the invention provides a surgical assembly comprising a surgical device of the invention and a wound retractor.

In one embodiment the device is releasably mountable to the retractor.

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In another embodiment the device is integral with the retractor.

The invention also provides in another aspect a surgical device comprising:-

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a retracting member movable from an insertion configuration to a retracting configuration to retract laterally a wound opening; and

- 5 -

a sealing member for sealing a retracted wound opening;

5 the sealing member having at least two accessways to facilitate sealed access through a retracted wound opening.

In one embodiment of the invention the sealing member comprises at least one chamber for receiving pressurised fluid to seal at least one accessway.

10 Preferably the sealing member comprises at least one iris valve to seal at least one accessway.

The sealing member may comprise at least one lip seal to seal at least one accessway.

15 The sealing member is preferably rotatable in a sealed manner relative to the retracting member.

In another aspect the invention provides a surgical device comprising:-

20 a retracting member movable from an insertion configuration to a retracting configuration to retract laterally a wound opening; and

a sealing member for sealing a retracted wound opening;

25 the sealing member being rotatable in a sealed manner relative to the retracting member.

In one case the sealing member is releasably mounted to the retracting member.

30 The device may comprise a proximal member for location externally of a wound opening, the proximal member being movable relative to the retracting member to

- 6 -

move the retracting member to the retracting configuration. Preferably the proximal member comprises an annular ring means. Ideally the annular ring means comprises an inner ring and an outer ring between which the retracting member may be led.

5 The sealing member may be at least partially transparent.

#### Brief Description of the Drawings

10 The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a partially cross-sectional, front view of a surgical device according to the invention, in use;

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Fig. 2 is an exploded, perspective view of a seal of the device of Fig. 1;

Fig. 3 is a plan view of the seal of Fig. 2;

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Figs. 4 and 5 are partially cross-sectional, front views of the seal of Fig. 2, in use;

Figs. 6 and 7 are views similar to Figs. 2 and 3 of another seal according to the invention;

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Fig. 8 is a cross-sectional, front view of the seal of Figs. 6 and 7;

Figs. 9 to 11 are views similar to Figs. 6 to 8 of another seal according to the invention;

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- 7 -

Fig. 12 is a partially cross-sectional, front view of the seal of Figs. 9 to 11, in use;

5 Figs. 13 and 14 are views similar to Figs. 9 and 11 of another seal according to the invention;

Figs. 15 to 17 are views similar to Figs. 6 to 8 of another seal according to the invention;

10 Figs. 18 to 20 are partially cross-sectional, front views of the seal of Figs. 15 to 17, in use;

Figs. 21 and 22 are exploded, perspective views of other seals according to the invention;

15 Fig. 23 is a cross-sectional, front view of a further seal according to the invention;

Fig. 24 is an exploded, perspective view of the seal of Fig. 23;

20 Fig. 25 is a perspective view of another seal according to the invention;

Fig. 26 is a perspective view of the seal of Fig. 25, in use;

25 Figs. 27 and 28 are views similar to Figs. 25 and 26 of another seal according to the invention;

Fig. 29 is a perspective view of another seal of the device of Fig. 1;

30 Figs. 30 and 31 are perspective views of the seal of Fig. 29, in use;

- 8 -

Fig. 32 is an exploded, perspective view of another surgical device according to the invention;

Fig. 33 is a plan view of the device of Fig. 32;

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Fig. 34 is a perspective view of the device of Fig. 32, in use;

Fig. 35 is a partially cross-sectional, front view of the device of Fig. 32, in use;

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Figs. 36 and 37 are plan views of the device of Fig. 32, in use;

Figs. 38 to 40 are plan views of other surgical devices according to the invention;

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Fig. 41 is a plan view of a further surgical device according to the invention, in use;

Figs. 42 and 43 are perspective views of other surgical devices according to the invention; and

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Fig. 44 is a perspective view of the device of Fig. 43, in use.

### Detailed Description

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Referring to Fig. 1 there is illustrated a surgical device 1 according to the invention. The device 1 has a proximal seal 2 which is normally open, and a distal seal 3 which is normally closed. This dual seal arrangement facilitates passage of an object, such as a surgeon's forearm 4, through the device 1 into a body cavity in a sealed manner. The surgical device 1 may thus be used to maintain pneumoperitoneum during hand-assisted laparoscopic surgery.

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In this case, the proximal seal 2 is provided in the form of a lip seal.

5 Figs. 2 to 5 illustrate the distal seal 3 in further detail. The distal seal 3 comprises three sealing members 5, 6, 7. In this case, each sealing member 5, 6, 7 is provided in the form of a sheet coupled to a circumferentially extending O-ring 8.

Each sealing member 5, 6, 7 has an accessway 9, 10, 11 respectively to facilitate access from one side of the sealing member to the other side of the sealing member. 10 The accessways 9, 11 are provided in the form of circular openings through the sealing members 5, 7 located centrally in the sealing members 5, 7. The accessway 10 is provided in the form of a crescent-shaped passageway at the edge of the sealing member 6.

15 As illustrated in Fig. 2, the opening 9 is offset from the passageway 10, and the passageway 10 is offset from the opening 11. In this manner the sealing members 5, 6, 7 are normally closed to prevent leakage of insufflation gas through the distal seal 3.

The sealing members 5, 6, 7 are manipulable to facilitate alignment of the accessways 9, 10, 11, as illustrated in Fig. 4. When the accessways 9, 10, 11 have been aligned, 20 the surgeon's hand and arm 4 may be passed through the distal seal 3 to gain access to an internal body cavity and/or internal body organs, as illustrated in Fig. 5.

25 A suitable material for the sealing members 5, 6, 7 to enable manipulation of the sealing members 5, 6, 7 is a flexible material, such as silicone or latex. The sealing members 5, 6, 7 are preferably also of a resilient material to ensure that the sealing members 5, 6, 7 return to the normally closed position after withdrawal of the surgeon's arm 4.

- 10 -

In Figs. 6 to 8 there is illustrated another distal seal 20 according to the invention, which is similar to the distal seal 3 of Figs. 1 to 5, and similar elements in Figs. 6 to 8 are assigned the same reference numerals.

5 In this case the distal seal 20 comprises an arcuate magnet 21 coupled to a proximal surface of the proximal sealing member 5, and an arcuate magnet 22 coupled to a distal surface of the distal sealing member 7. The magnets 21, 22 act to bias the sealing members 5, 7 towards one another with the middle sealing member 6 sandwiched in between. This magnetic arrangement enhances the gas-tight seal  
10 achieved by the distal seal 20.

Referring to Figs. 9 to 12 there is illustrated another distal seal 30 according to the invention, which is similar to the distal seal 3 of Figs. 1 to 5, and similar elements in Figs. 9 to 12 are assigned the same reference numerals.

15 In this case, each accessway 31, 32, 33 is provided in the form of a passageway at the edge of the sealing member 5, 6, 7 respectively. The middle passageway 32 is offset from the proximal and distal passageways 31, 33 respectively. In this manner the sealing members 5, 6, 7 are normally closed to prevent leakage of insufflation gas  
20 through the distal seal 30.

Use of the distal seal 30 proceeds in a manner similar to that described previously with reference to the distal seal 3 of Figs. 1 to 5.

25 Figs. 13 and 14 illustrate a further distal seal 40 according to the invention, which is similar to the distal seal 30 of Figs. 9 to 12, and similar elements in Figs. 13 and 14 are assigned the same reference numerals.

The distal seal 40 comprises a magnet 41 coupled to the proximal surface of the  
30 proximal sealing member 5, and a magnet 42 coupled to the distal surface of the distal

- 11 -

sealing member 7, in a manner similar to that described previously with reference to the distal seal 20 of Figs. 6 to 8.

Referring to Figs. 15 to 20 there is illustrated another distal seal 50 according to the invention which is suitable for use with the surgical device 1.

The distal seal 50 comprises two sealing members 51, 52 and a spherical ball 56. In this case each sealing member 51, 52 is provided in the form of a sheet coupled to a circumferentially extending O-ring 53.

Each sealing member 51, 52 has an accessway 54, 55 respectively to facilitate access from one side of the sealing member to the other side of the sealing member. The accessways 54, 55 are provided in the form of circular openings through the sealing members 51, 52 located centrally in the sealing members 51, 52. As illustrated in Figs. 15 and 16, the accessways 54, 55 are aligned.

The ball 56 is located between the two sealing members 51, 52, as illustrated in Fig. 17. As illustrated in Fig. 18, the ball 56 is movable laterally within the two sealing members 51, 52 from a sealing position in which the ball 56 occludes the two accessways 54, 55 (Fig. 17), to an access position in which the accessways 54, 55 are open for passage of the surgeon's arm 4 therethrough (Figs. 19 and 20).

When the ball 56 is in the sealing position (Fig. 17), the distal seal 50 prevents escape of insufflation gas from a body cavity. When the ball 56 is in the access position (Figs. 19 and 20), the distal seal 50 facilitates sealed access of the surgeon's arm 4 through the distal seal 50 to the body cavity.

The ball 56 may be tethered to the O-ring 53 by means of a tether line 61, as illustrated in the distal seal 60 of Fig. 21. The tether line 61 thus prevents inadvertent passage of the ball 61 out from between the sealing members 51, 52 through one of the accessways 54, 55.

In the distal seal 70 of Fig. 22, the ball 56 is connected to the O-ring 53 by three resilient members 71, 72, 73, for example elastic bands. The resilient members 71, 72, 73 act to bias the ball 56 towards the central sealing position occluding the two accessways 54, 55. In this manner, upon removal of the surgeon's arm 4 from the distal seal 70, the ball 56 is moved back to the sealing position to prevent loss of insufflation gas from the body cavity.

A collar 81 may be provided around the accessway 81 on the proximal surface of the proximal sealing member 51, as illustrated in Figs. 23 and 24. It has been found that such a collar arrangement enhances the sealing of the ball 56 to the sealing member 51 around the opening 54.

In Figs. 25 and 26 there is illustrated another distal seal 96 according to the invention, which is suitable for use with the surgical device 1.

The distal seal 96 comprises two sealing members 90, 91. In this case each sealing member 90, 91 is provided in the form of a sheet coupled to a circumferentially extending O-ring 92.

The sealing members 90, 91 overlap one another such that a portion of the sealing member 90 overlaps a portion of the sealing member 91 along a first overlap region 94, and a portion of the sealing member 91 overlaps a portion of the sealing member 90 along a second overlap region 93, as illustrated in Fig. 26. In this manner the distal seal 96 is normally closed to prevent escape of insufflation gas between the sealing members 90, 91 (Fig. 25).

The sealing members 90, 91 are manipulable to facilitate sealed passage of an object, such as the surgeon's arm 4, through the distal seal 96 at the junction 95 of the two overlap regions 93, 94 to gain access to an internal body cavity and/or internal body organs, as illustrated in Fig. 26.

- 13 -

A suitable material for the sealing members 90, 91 to enable manipulation of the sealing members 90, 91 is a flexible material, such as silicone or latex. The sealing members 90, 91 are preferably also of a resilient material to ensure that the sealing members 90, 91 return to the normally closed position after withdrawal of the surgeon's arm 4.

In this case the area of the two overlap regions 93, 94 is substantially equal.

Referring next to Figs. 27 and 28, there is illustrated another distal seal 100 according to the invention, which is suitable for use with the surgical device 1.

The seal 100 comprises a sleeve 101 through which an object, such as a surgeon's arm 4, may be passed and an annular platform 102. The platform 102 has an O-ring 103 to stiffen the platform 102.

The sleeve 101 is configured to curl-up upon itself as illustrated in Fig. 27, and thereby bias itself into a normally closed configuration. In this closed configuration the curled sleeve 101 prevents the escape of insufflation gas from a body cavity through the distal seal 100.

To gain access to an internal body cavity or internal body organs, the surgeon inserts his arm 4 through the sleeve 101 which causes the sleeve 101 to uncurl (Fig. 28).

It will be appreciated that other self-closing configurations are possible for the sleeve 101. For example, the sleeve 101 may alternatively be configured to twist-up upon itself to the closed configuration.

It will be understood that a wide variety of possible configurations for the proximal seal of the surgical device 1 are possible within the scope of this invention. For

- 14 -

example, the proximal seal may comprise an iris valve 110, as illustrated in Figs. 29 and 30.

5 The proximal seal may additionally or alternatively be in the form of one of the seals described previously with reference to Figs. 2 to 28.

Furthermore it will be appreciated that the surgical device 1 and the seals according to the invention are suitable for sealing a variety of objects, such as a surgical instrument 120, as illustrated in Fig. 31.

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The surgical device 1 of the invention could be used in configuration with a wound retractor. In one case the device 1 could be releasably mounted to the retractor. In another case the device 1 could be provided integral with the retractor.

15 Referring now to Figs. 32 to 37 there is illustrated another surgical device 130 according to the invention.

The device 130 comprises a wound retractor 131 and a domed sealing member 132.

20 The wound retractor 131 is similar to the surgical wound retractor described in international patent application number PCT/IE00/00126, the relevant contents of which are incorporated herein by reference. In particular, the retractor 131 comprises a distal O-ring 139 for insertion into a wound opening 138, a retracting sleeve 135, and a proximal annular ring means.

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The proximal annular ring means comprises an outer ring 141 and an inner O-ring 140 which is partially located in a recess of the outer ring 141. The sleeve 135 passes through the proximal annular ring means between the inner and outer rings 140, 141 (Fig. 35).

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- 15 -

To retract the wound opening 138, the distal O-ring 139 is inserted into the wound opening 138 to another the wound retractor 131 in position in the wound opening 138. The proximal rings 140, 141 are then moved downwardly while pulling the sleeve 135 upwardly to move the sleeve 135 lining the wound laterally to a retracting configuration, and thereby retract the sides of the wound opening 138 laterally.

The sealing member 132 comprises two accessways 136, 137 through the sealing member 132, through which the left and right arms 133, 134 of a surgeon may be extended to gain access to an internal body cavity or internal body organs.

By providing two access openings 136, 137 in the sealing member 132, this enables the surgeon to extend both arms 133, 134 through the retracted wound opening 138 in a sealed manner. Thus it is possible for the surgeon to perform procedures with both hands, such as suturing, while maintaining the pneumoperitoneum.

The sealing member 132 is releasably mounted to the wound retractor 131 in a retractable manner. Thus as illustrated in Figs. 36 and 37, it is relatively simple to rotate the sealing member 132 and thus the accessways 136, 137 to enable the surgeon access a desired region or organ within the sealed internal body cavity.

It will be appreciated that means may be provided to seal the accessways 136, 137 when not in use, and to seal around an object, such as the surgeon's arms 133, 134, extending through the accessways 136, 137.

In the surgical device 150 of Fig. 38, lip seals 151 are provided at each accessway 136, 137 to effect the sealing function.

In the surgical device 160 of Fig. 39, each accessway 136, 137 has an inflatable chamber 161. By passing a pressurised fluid into the chamber 161 the accessways 136, 137 may be sealed. In this case the chamber 161 is defined by a sleeve turned back on itself to define an outer sleeve section and an inner sleeve section with the

- 16 -

chamber defined therebetween. The inner sleeve section is twisted and the outer sleeve section is substantially cylindrical. Upon passage of an object, such as the surgeon's arms 133, 134 through the inflated sleeve, the sleeve everts. In this regard the chamber 161 is similar to the medical device described in International patent application number PCT/IE99/00123, the relevant contents of which are incorporated herein by reference.

In the surgical device 170 of Fig. 40, iris valves 171 are provided at each accessway 136, 137 to effect the sealing function.

As illustrated in the surgical device 180 of Fig. 41, the sealing member 181 may be at least partially transparent for enhanced visualisation of the sealed internal body cavity and/or internal body organs.

It will be appreciated that the surgical devices according to the invention may also be configured to seal objects other than a human arm extended through an accessway of the sealing member 132, for example a surgical instrument.

Furthermore an accessway 192 may be provided through the sealing member 132 for a surgical instrument 191 in addition to the two arm accessways 136, 137, as illustrated in the surgical device 190 of Fig. 42.

As a further alternative a bag 201 may be attached to the sealing member 132 at a bag opening 202, as illustrated in the surgical device 200 of Figs. 43 and 44. The bag 201 is gas-tightly sealed to the sealing member 132 at the opening 202 to maintain the pneumoperitoneum. An internal organ of the patient, such as portion of the colon 203, may be temporarily moved into the bag 201 for closer examination and/or to create extra space within the body cavity.

- 17 -

The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.